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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/384,379	08/27/1999	YOSUKE AOKI	2167-0110P	7722

2292 7590 05/15/2002

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 05/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/384,379

Applicant(s)

AOKI ET AL

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Applicant's response filed 28 February 2002 has been received. Claims 1-5 are pending.
2. All rejections not reiterated herein below are withdrawn.
3. The text of those US codes not found in this office action may be found in a previous office action.

### *Claim Rejections - 35 USC § 103*

4. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al (Clinica Chimica Acta, 178:193-204, 1988) in view of Kohler (Science, 233:1281-1286, 1986) for reasons of record in the previous office action.

### *Response to Arguments*

5. Applicant argues that Aoki fail to disclose the use of a monoclonal antibody that specifically recognizes medullasin and Kohler fails to disclose the production of a monoclonal antibody against the human medullasin. Therefore, Kohler and Aoki have absolutely nothing in common regarding their teachings and disclosure. Applicant argues that because the references are so unrelated, one of ordinary skill in the art would not look to this disclosure to come up with the instant invention. Applicant further argues that neither reference hints at producing a monoclonal antibody that specifically recognizes the human medullasin. And lastly, applicant argues that polyclonal antibodies are very different from monoclonal antibodies and that monoclonal antibodies have a stronger specificity to an antigen as compared to polyclonal antibodies.

These arguments have been fully considered but are not deemed to be persuasive. Aoki clearly recognizes the importance of detecting human medullasin and relating their activities to diseases such as multiple sclerosis. Aoki also clearly recognizes the usefulness of medullasin in both diagnosing and evaluating MS. Aoki discloses polyclonal antibodies for use in an assay to detect medullasin. Kohler, on the other hand, teaches that any substance that can elicit a humoral response can be used to prepare monoclonal antibodies, and that monoclonal antibodies provide advantages not found with polyclonal antibodies. Therefore, one of ordinary skill in the art, in looking for a more sensitive assay to detect medullasin, would have been motivated to make and use monoclonal antibodies that specifically recognizes and binds to human medullasin. As evidence in

Hybritech Incorporated v. Monoclonal Antibodies, Inc. CA FC 231 USPQ 81 (9/19/1986), the principle for the production of monoclonal antibodies is so well known in the art that it is a routine matter. Further, monoclonal antibodies have been recognized as providing advantages that are not present in polyclonal antibodies, therefore, there is a clear showing of a reasonable expectation of success and one of ordinary skill in the art would have been motivated to use the techniques of Kohler to produce monoclonal antibodies to a well known protein, such as human medullasin. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a monoclonal antibody against human medullasin using the method of Kohler because Kohler teaches that any substance that can elicit a humoral response can be used to prepare monoclonal antibodies, and that monoclonal antibodies provides advantages not found in polyclonal antibodies. These advantages include specificity of binding, homogeneity, and ability to be produced in unlimited quantities. The production of monoclonal antibodies allows the isolation of reagents with a unique and chosen specificity.

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Because all of the antibodies produced by descendants of one hybridoma cell are identical, monoclonal antibodies are powerful reagents for testing for the presence of a desired epitope. In addition, one unique advantage of hybridoma production is that impure antigens can be used to produce specific antibodies

### *Conclusion*

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

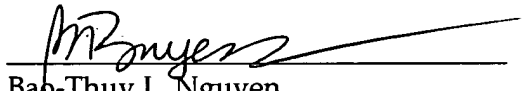
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
May 14, 2002